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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 98N-0182
21 CFR 216
4-Aminopyridine (4-AP)

I respectfully request that the above substance be included on the list of "drugs" that can be compounded and dispensed for use under the exemptions of the FDA Act.

I have multiple sclerosis of the primary progressive type (PPMS). This adversely affects my walking and mobility.

As you know, there is no cure for MS. The new (expensive) "miracle" drugs Avonex, Betaseron and Copaxone (ABC Drugs) are for use by MS patients having the relapse recurring type (RRMS), which is totally different from PPMS. There is no similar drug for PPMS. 4-AP is not used by RRMS patients, which are by far the largest group of MSers.

I have been using 4-AP for about four years. It has been of significant help to me during this period of time in a number of respects. Particularly, after taking the substance I have increased mobility and functionality. It also improves my overall energy level. I know it is not a cure but it is the only thing available which provides any help at all to those of us with PPMS.

I have taken 4-AP in several different forms, direct liquid, time release, and regular capsules. I have found all forms of administration to be helpful. I have NEVER had any adverse reaction of any type.

Further, 4-AP is relatively inexpensive. This is one of the few drug

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type products I have used where I truly feel that I am getting value for my money. I suspect that the low price of the substance, the relatively small market and the fact that no patent is available, explains the lack of interest of major drug companies in producing and marketing 4-AP.

The Preliminary Report of the Advisory Committee (page 23) states that inclusion of the substance on the bulk drugs list is questionable until "more information is available about the historical use and safety of 4-AP". If the FDA is looking for the usual mass of data and studies that it requires to approve a drug, then this sounds the death knell for 4-AP and the benefits it affords those of us with PPMS. Because of the limited financial reward, as discussed above, a drug company will not spend the large amount of money needed to acquire such data.

In a conversation with Ms Topper, the Committee Executive Secretary, on November 3, 1998, she advised that the FDA was considering making 4-AP available on an individual IND basis. Most of us can't afford the time, trouble and expense of such a procedure. We have limited resources, both financial and physical.

In summary, **please leave us alone** !! Why take away a product that gives some relief where none is otherwise available? If you really want to do something positive, lean on the ABC Drug manufacturers to supply 4-AP at today's prevailing prices. Lord knows they make enough profit from what the FDA has approved based on statistical analysis of subjective data.

Sincerely,

Gordon D. Coplein

cc: Committee Members
Senator Paul Coverdell
Senator Max Cleland
Rep. Cynthia McKinney